

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF Art Unit:
CHANG ET AL. Examiner:
APPLICATION NO: TBA (div. of 08/974,391) Atty. Docket: 4-31401A
FILED: Herewith
FOR: VECTORS FOR TISSUE-SPECIFIC REPLICAITON AND GENE
EXPRESSION

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

This paper is being filed within three months of the filing date of the application. Therefore, no fees are required. If a fee is deemed to be required, the Commissioner is hereby authorized to charge such fee to Deposit Account No. 19-0134.

In accordance with 37 C.F.R. §1.56, applicants wish to call the Examiner's attention to the references cited on the attached form(s) PTO-1449.

. The listed references are of record in parent Application No. 08/974,391 filed November 19, 1997, and in related applications 08/487,992, filed June 7, 1995, 08/348,258, filed November 28, 1994, 08,849,117, filed July 1, 1997, and PCT/US95/15455, filed November 28, 1995, and copies are available therein. However, applicants are willing to send copies of any or all of these references at the Examiner's request.

The Examiner is requested to consider the foregoing information in relation to this application and indicate that each reference was considered by returning a copy of the initialed PTO 1449 form(s).

Respectfully submitted,


J. Timothy Meigs
Attorney for Applicants
Reg. No. 38,241

Novartis
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Date: June 24, 2003

(Use several sheets if necessary)

ATTY. DOCKET NO.
4-31401A
APPLICATION NO.APPLICANT
CHANG ET AL.
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Group

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	AA	2001/0053768 A1	12/20/03	Gregory, et al.			12/16/98
	AB	2002/0068049 A1	6/6/02	Henderson, et al.			12/6/00
	AC	5,112,767	5/12/92	Roy-Burman, et al.			3/4/88
	AD	5,324,664	6/28/94	Nunberg, et al.			1/21/93
	AE	5,358,866	10/25/94	Mullen, et al.			7/3/91
	AF	5,416,017	5/16/95	Burton, et al.			3/25/93
	AG	5,436,146	7/25/95	Shenk, et al.			1/21/93
	AH	5,529,774	6/25/96	Barba, et al.			8/13/91
	AI	5,585,096	12/17/96	Martuza, et al.			6/23/94
	AJ	5,585,254	12/17/96	Maxwell, et al.			4/2/93
	AK	5,591,439	1/7/97	Plotkin, et al.			4/21/95
	AL	5,601,818	2/11/97	Freeman, et al.			12/8/94

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	OFFICE	CLASS	SUBCLASS	TRANSLATION YES NO
	AM	EP 0 415 731 A3	3/6/91	Europe			<input type="checkbox"/> <input type="checkbox"/>
	AN	EP 0 476 953	3/25/92	Europe			<input type="checkbox"/> <input type="checkbox"/>
	AO	EP 0 514 603	11/25/92	Europe			<input type="checkbox"/> <input type="checkbox"/>
	AP	WO 90/05180	5/17/90	WIPO			<input type="checkbox"/> <input type="checkbox"/>
	AQ	WO 92/03563 A1	3/5/92	WIPO			<input type="checkbox"/> <input type="checkbox"/>

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

AR	Abe, et al., "Characterization of cis-acting Elements Regulating Transcription of the Human DF3 Breast Carcinoma-associated Antigen (MUC1) Gene," <i>Proc. Natl. Acad. Sci. USA</i> , 90:282-286 (January 1993)
AS	Babiss, et al., "Cellular Promoters Incorporated into the Adenovirus Genome: Effect of Viral DNA Replication on Endogenous and Exogenous Gene Transcription," <i>J. Mol. Biol.</i> , 193:643-650 (1987)
AT	Berkner, K.L., "Development of Adenovirus Vectors for the Expression of Heterologous Genes," <i>BioTechniques</i> , 6:616-629 (1988)

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	AA	5,624,820	4/29/97	Cooper			6/7/95
	AB	5,624,830	4/29/97	Mullen, et al.			7/7/94
	AC	5,631,236	5/20/97	Woo, et al.			8/26/93
	AD	5,677,178	10/14/97	McCormick, F.			4/29/96
	AE	5,691,177	11/25/97	Guber, et al.			6/5/95
	AF	5,698,443	12/16/97	Henderson, et al.			6/27/95
	AG	5,728,379	3/17/98	Martuza, et al.			6/7/95
	AH	5,747,469	5/5/98	Roth, et al.			4/25/94
	AI	5,801,029	9/1/98	McCormick, F.			6/7/95
	AJ	5,804,407	9/8/98	Tamaoki, et al.			11/4/93
	AK	5,830,686	11/3/98	Henderson, D.R.			1/13/94
	AL	5,846,945	12/8/98	McCormick, F.			6/7/95

FOREIGN PATENT DOCUMENTS

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	AM	WO 93/09239	5/13/93	WIPO			<input type="checkbox"/> <input type="checkbox"/>
	AN	WO 93/10218	5/27/93	WIPO			<input type="checkbox"/> <input type="checkbox"/>
	AO	WO 94/13824	6/23/94	WIPO			<input type="checkbox"/> <input type="checkbox"/>
	AP	WO 94/18992	9/1/94	WIPO			<input type="checkbox"/> <input type="checkbox"/>
	AQ	WO 95/05835	3/2/95	WIPO			<input type="checkbox"/> <input type="checkbox"/>

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

AR	Blaese, et al., "In situ Delivery of Suicide Genes for Cancer Treatment," <i>Eur. J. Cancer</i> , 30A(8):1190-1193 (August 1994)
AS	Boviatsis, et al., "Antitumor Activity and Reporter Gene Transfer into Rat Brain Neoplasms Inoculated With Herpes Simplex Virus Vectors Defective in Thymidine Kinase or Ribonucleotide Reductase," <i>Gene Therapy</i> , 1:323-331 (September 1994)
AT	Brown, D., "Gene Therapy 'Oversold' by Researchers, Journalists," <i>The Washington Post</i> , p. A22 (December 8, 1995)

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	AA	5,856,181	1/5/99	McCormick, F.			10/14/9
	AB	5,871,726	2/16/99	Henderson, et al.			6/26/96
	AC	5,919,652	7/6/99	Pang, et al.			9/1/95
	AD	5,965,124	10/12/99	Feinberg			1/31/95
	AE	5,998,205	12/7/99	Hallenbeck, et al.			7/1/97
	AF	6,051,417	4/18/00	Henderson, et al.			8/4/97
	AG	6,057,299	5/2/00	Henderson, D.R.			9/27/96
	AH	6,080,578	6/27/00	Bischoff, et al.			12/8/97
	AI	6,133,243	10/17/00	Kirn, D.			2/22/96
	AJ	6,136,792	10/24/00	Henderson, D.R.			7/11/97
	AK	6,197,293	3/6/01	Henderson, et al.			3/2/98
	AL	6,254,862	7/3/01	Little, et al.			3/2/98

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	AM	WO 95/11984	5/4/95	WIPO			<input type="checkbox"/> <input type="checkbox"/>
	AN	WO 95/12660	5/11/95	WIPO			<input type="checkbox"/> <input type="checkbox"/>
	AO	WO 95/14102	5/26/95	WIPO			<input type="checkbox"/> <input type="checkbox"/>
	AP	WO 95/25807	9/28/95	WIPO			<input type="checkbox"/> <input type="checkbox"/>
	AQ	WO 96/01642	1/25/96	WIPO			<input type="checkbox"/> <input type="checkbox"/>

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

AR	Chambers, et al., "Comparison of Genetically Engineered Herpes Simplex Viruses for the Treatment of Brain Tumors in a Scid Mouse Model of Human Malignant Glioma," <i>Proc. Natl. Acad. Sci. USA</i> , 92:1411-1415 (February 1995)
AS	Chellappan, et al., "Adenovirus E14, Simian Virus 40 Tumor Antigen, and Human Papillomavirus E7 Protein Share the Capacity to Disrupt the Interaction Between Transcription Factor E2F and the Retinoblastoma Gene Product," <i>Proc. Natl. Acad. Sci. USA</i> , 89:4549-4553 (1992)
AT	Chen, et al., "Gene Therapy for Brain Tumors: Regression of Experimental Gliomas by Adenovirus-Mediated Gene Transfer In Vivo," <i>Proc. Natl. Acad. Sci. USA</i> , 91:3054-3057 (April 1994)

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U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	AA	6,296,845	10/2/01	Sampson-Johannes, et al.			11/12/98
	AB	6,432,700	8/13/02	Henderson, et al.			3/2/98
	AC	6,551,587	4/22/03	Hallenbeck, et al.			12/15/9
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	AM	WO 96/14875	5/23/96	WIPO			<input type="checkbox"/>	<input type="checkbox"/>
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	AP	WO 96/33282	10/24/96	WIPO			<input type="checkbox"/>	<input type="checkbox"/>
	AQ	WO 96/34969	11/7/96	WIPO			<input type="checkbox"/>	<input type="checkbox"/>

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

AR	Coghlan, A., "Gene Dream Fades Away," New Scientist, 145:14-15 (November 1995)
AS	Cornelis, et al., "Transformation of Human Fibroblasts by Ionizing Radiation, a Chemical Carcinogen, or Simian Virus 40 Correlates with an Increase in Susceptibility to the Autonomous Parvoviruses H-1 Virus and Minute Virus of Mice," J. Virol., 62(5):1679-1686 (1988)
AT	Crystal, R.G., "Transfer of Genes to Humans: Early Lessons and Obstacles to Success," Science, 270:404-410 (October 1995)

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AN	WO 97/01358	1/16/97	WIPO				<input type="checkbox"/> <input checked="" type="checkbox"/>
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AP	WO 98/35028	8/13/98	WIPO				<input type="checkbox"/> <input checked="" type="checkbox"/>
AQ	WO 98/39465	9/11/98	WIPO				<input type="checkbox"/> <input checked="" type="checkbox"/>

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

AR	Culver, et al., "In Vivo Gene Transfer with Retroviral Vector-Producer Cells for Treatment of Experimental Brain Tumors," <i>Science</i> , 256:1550-1552 (1992)
AS	de Foresta, et al., "La Transformation Par Le Virus SV40 Sensibilise Les Fibroblastes de Peu Human a L'action Lytique du Parvovirus H-I," <i>C.R. Soc. Biol.</i> , 179:276-282 (1985)
AT	Dillon, N., "Regulating Gene Expression in Gene Therapy," <i>TIBTECH</i> , 11:167-173 (1993)

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FORM PTO-1449
(REV. 7-85)

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	AM	WO 98/39466	9/11/98	WIPO			<input type="checkbox"/> <input checked="" type="checkbox"/>
	AN	wo 98/39467	9/11/98	WIPO			<input type="checkbox"/> <input checked="" type="checkbox"/>
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	AP						<input type="checkbox"/> <input checked="" type="checkbox"/>
	AQ						<input type="checkbox"/> <input checked="" type="checkbox"/>

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

AR	Dooley, et al., "Transactivation of the Adenovirus Ella Promoter in the Absence of Adenovirus E1A Protein is Restricted to Mouse Oocytes and Preimplantation Embryos," <i>Development</i> , 107:945-956 (1989)
AS	Dynan, W.S., "Modularity in Promoters and Enhancers," <i>Cell</i> , 58:1-4 (1989)
AT	Eiselein, et al., "Treatment of Transplanted Murine Tumors with an Oncolytic Virus and Cyclophosphamide," <i>Can. Res.</i> , 38:3817-3822 (1978)

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

	AA	Fattaey, et al., "Replication of Adenovirus Mutants in Human Cancer Cells," Abstracts of papers presented at the 1994 meeting on Molecular Biology of Papovaviruses and Adenoviruses, August 17-21, 1994, Cold Spring Laboratory, Cold Spring Harbor, New York.
	AB	Fresen, et al., "Elektrokinetisches Verhalten von Ehrlich-Aszites-Tumorzellen nach Infektion mit Onkolytischem Influenzavirus," <i>Path. Microbiol.</i> (Basel), 40:227-228 (1974)
	AC	Fresen, et al., "Physicochemical Membrane Changes in Ehrlich Ascites Tumor Cells Infected with Oncolytic Influenza Virus," <i>Arch. Gesamte Virusforsch.</i> , 41:267-276 (1973)
	AD	Fresen, K.O., "Physikochemische Veränderungen der Zelloberfläche von Ehrlich Aszites-Tumorenzellen nach Infektion mit Onkolytischem Influenza-Virus," <i>Zentralbl. Bakt. Hyg. I.Abt. Orig. A.</i> , 227:409-413 (1974)
	AE	Freytag, et al., "A Novel Three-Pronged Approach to Kill Cancer Cells Selectively: Concomitant Viral, Double Suicide Gene, and Radiotherapy," <i>Human Gene Therapy</i> , 9:1323-1333 (June 1998)
	AF	Friedman, et al., "Adenoviral Vectors and Liver Specific Gene Control," <i>Transcriptional Control Mechanisms</i> , 421-435 (1987)
	AG	Friedman, et al., "Cellular Promoters Incorporated into the Adenovirus Genome: Cell Specificity of Albumin and Immunoglobulin in Expression," <i>Molec. Cell. Biol.</i> , 6(11):3791-3797 (1986)
	AH	Fujiwara, et al., "A Retroviral Wild-type p53 Expression Vector Penetrates Human Lung Cancer Spheroids and Inhibits Growth by Inducing Apoptosis," <i>Can. Res.</i> , 53:4129-4133 (September 1993)
	AI	Furukawa, et al., "Effect of Virus-modified Tumor Cell Extracts, Autologous Mononuclear Cell Infusions and Interleukin-2 Oncolytic Activity of Effector Cells of Patients with Advanced Ovarian Cancer," <i>Cancer Immunol. Immunother.</i> , 30:126-132 (1989)
	AJ	Gerard, et al., "Adenovirus-Mediated Gene Transfer," <i>TCM</i> , 3(5):171-177 (May 1993)
	AK	Gordon, et al., "Gene Therapy Using Retroviral Vectors," <i>Curr. Op. Biotechnol.</i> , 5:611-616 (December 1994)
	AL	Graham, F.L., "Growth of 293 Cells in Suspension Culture," <i>J. Gen. Virol.</i> , 68:937-940 (1987)
	AM	Grooteclaes, et al., "The 6-Kilobase c-erbB2 Promoter Contains Positive and Negative Regulatory Elements Functional in Human Mammary Cell Lines," <i>Cancer Res.</i> , 54:4193-4199 (August 1994)
	AN	Gunzburg, et al., "Mouse Mammary Tumor Virus Mediated Transfer and Expression of Neomycin Resistance to Infected Cultured Cells," <i>Virology</i> , 155:236-248 (1986)

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

	AA	Gunzburg, et al., "Virus Vector Design in Gene Therapy," <i>Molec. Med. Today</i> , 1(9):410-417 (December 1995)
	AB	Haj-Ahmad, et al., "Development of a Helper-Independent Human Adenovirus Vector and Its Use in the Transfer of the Herpes Simplex Virus Thymidine Kinase Gene," <i>J. Virol.</i> , 57:267-274 (1986)
	AC	Hallenbeck, et al., "A Novel Tumor-Specific Replication-Restricted Adenoviral Vector for Gene Therapy of Hepatocellular Carcinoma," <i>Hum. Gene Ther.</i> , 10:1721-1733 (July 1999)
	AD	Hallenbeck, et al., "Novel Tumor Specific Replication Competent Adenoviral Vectors for Gene Therapy of Cancer," from the Fifth International Conference on Gene Therapy of Cancer, San Diego, CA, November 14-16, 1996, <i>Cancer Gene Ther.</i> , 3:s19 (November 1996)
	AE	Hallenbeck, et al., "Novel Tumor Specific Replication Restricted Adenoviral Vector for Gene Therapy of Liver Cancer," from the Sixth International Conference on Gene Therapy of Cancer, San Diego, CA, November 20-22, 1997, <i>Cancer Gene Ther.</i> , 4:s22 (November 1997)
	AF	Harris, et al., "Gene Therapy for Cancer Using Tumor-Specific Prodrug Activation," <i>Gene Therapy</i> , 1:170-175 (May 1994)
	AG	Hitt, et al., "Adenovirus E1A Under the Control of Heterologous Promoters: Wide Variation in E1A Expression Levels Has Little Effect on Virus Replication," <i>Virology</i> , 179:667-678 (1990)
	AH	Hodes, et al., "Tissue Culture and Animal Studies with an Oncolytic Bovine Enterovirus (Bovine Enterovirus 1)," <i>Cancer Res.</i> , 33:2408-2414 (1973)
	AI	Horvath, et al., "Complementation of Adenovirus Early Region 1a and 2a Mutants by Epstein-Barr Virus Immortalized Lymphoblastoid Cell Lines," <i>Virology</i> , 184:141-148 (1991)
	AJ	Horwitz, M.S., "Adenoviral Diseases," <i>Virology</i> , 477-495 (1985)
	AK	Huber, et al., "Retroviral-Mediated Gene Therapy for the Treatment of Hepatocellular Carcinoma: An Innovative Approach for Cancer Therapy," <i>Proc. Natl. Acad. Sci. USA</i> , 88:8039-8043 (1991)
	AL	Imperiale, et al., "Common Control of the Heat Shock Gene and Early Adenovirus Genes: Evidence for a Cellular E1A-like Activity," <i>Molec. Cell. Biol.</i> , 4(5):867-874 (1984)
	AM	Jacotot, H., "Pouvoir Oncolytique in vivo du Virus de Newcastle a L'egard du Sarcome Ascitique de Yoshida," <i>C.R. Hebd. Seances Acad. Sci. Paris, Ser. D</i> , 264:2602-2603 (1967)
	AN	Kaneko, et al., "Adenovirus-Mediated Gene Therapy of Hepatocellular Carcinoma Using Cancer-Specific Gene Expression," <i>Canc. Res.</i> , 55:5283-5287 (November 1995)

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

	AA	Kenny, et al., "Viruses as Oncolytic Agents: A New Age for 'Therapeutic' Viruses," <i>J. Natl. Cancer Inst.</i> , 86:1185-1186 (August 1994)
	AB	Ko, et al., "Osteocalcin Promoter-based Toxic Gene Therapy for the Treatment of Osteosarcoma in Experimental Models," <i>Cancer Res.</i> , 56:4614-4619 (October 1996)
	AC	Kovarik, et al., "Analysis of the Tissue-specific Promoter of the MUC1 Gene," <i>J. Biol. Chem.</i> , 268:9917-9926 (May 1993)
	AD	La Thangue, et al., "An Adenovirus E1A-like Transcription Factor is Regulated During the Differentiation of Murine Embryonal Carcinoma Stem Cells," <i>Cell</i> , 49:507-513 (1987)
	AE	Ledley, F., "Nonviral Gene Therapy: The Promise of Genes as Pharmaceutical Products," <i>Hum. Gene Ther.</i> , 6:1129-1144 (September 1995)
	AF	Lewin, B., "Oncogenic Conversion by Regulatory Changes in Transcription Factors," <i>Cell</i> , 64:303-312 (1991)
	AG	Lorenz, et al., "Newcastle Disease Virus as an Antineoplastic Agent: Induction of Tumor Necrosis Factor- α and Augmentation of Its Cytotoxicity," <i>J. Natl. Cancer Inst.</i> , 80:1305-1312 (1988)
	AH	Manome, et al., "Enhancer Sequences of the DF3 Gene Regulate Expression of the Herpes Simplex Virus Thymidine Kinase Gene and Confer Sensitivity of Human Breast Cancer Cells to Ganciclovir," <i>Can. Res.</i> , 54:5408-5413 (October 1994)
	AI	Mastrangelo, et al., "Gene Therapy for Human Cancer: An Essay for Clinicians," <i>Seminars in Oncology</i> , 23(1):4-21 (February 1996)
	AJ	Max-Audit, et al., "Transcriptional Regulation of the Pyruvate Kinase Erythroid-specific Promoter," <i>J. Biol. Chem.</i> , 268:5431-5437 (March 1993)
	AK	Mettler, et al., "Virus Inoculation in Mice Bearing Ehrlich Ascitic Tumors: Antigen Production and Tumor Regression," <i>Infect. Immun.</i> , 37:23-27 (1982)
	AL	Miller, et al., "Progress in Transcriptionally Targeted and Regulatable Vectors for Genetic Therapy," <i>Human Gene Therapy</i> , 8:803-815 (May 1, 1997)
	AM	Missiro, et al., "Skin-specific Expression of a Truncated E1a Oncoprotein Binding to p105-Rb Leads to Abnormal Hair Follicle Maturation Without Increased Epidermal Proliferation," <i>J. Cell Biol.</i> , 121:1109-1120 (June 1993)
	AN	Moran, E., "Interaction of Adenoviral Proteins with pRB and p53," <i>FASEB J.</i> , 7:880-885 (July 1993)

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